



ENZYMATIC THERAPY INCORPORATED

What **Better** feels like.™

November 7, 2005

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	The three extracts in Better Bladder for Men are clinically studied to support a healthy bladder and urination.*	Nettle Root Extract, Pumpkin Seed Oil, Pygeum Bark Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

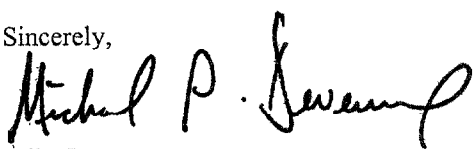
By: 
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/7/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,


Mike Devereux
Chief Financial Officer

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825 Challenger Drive, Green Bay, WI 54311-8328
P: 920.469.1313 • F: 888.570.6460 (Enzymatic)
P: 920.469.9099 • F: 920.469.4418 (Phyto)

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	Through their effects on prostate tissue health and the body's natural anti-inflammatory response, these extracts promote healthy bladder function.*	Nettle Root Extract, Pumpkin Seed Oil, Pygeum Bark Extract

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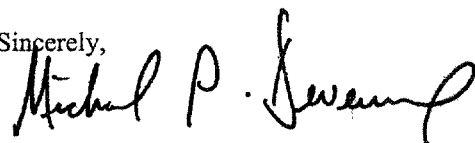
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	Pygeum contains key compounds known as phytosterols. These compounds, especially beta-sitosterol, have been known to support the body's natural anti-inflammatory response, especially in prostate tissue, as well as have immune supportive benefits.*	Pygeum Bark Extract

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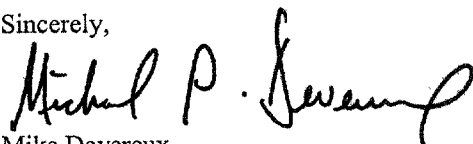
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	Scientific studies have found that pygeum extract supports healthy bladder smooth muscle tissue.*	Pygeum Bark Extract

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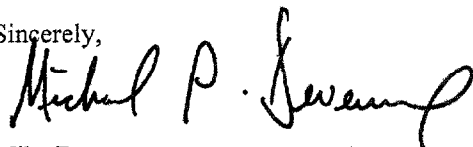
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	In a large placebo-controlled, double blind clinical trial, 263 men received either pygeum extract or placebo for 8 weeks. At the conclusion of the study, 66% of the men who had received pygeum extract experienced support for healthy micturition (urinary flow).*	Pygeum Bark Extract

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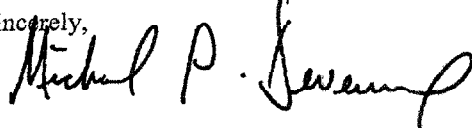
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	A meta analysis of 18 randomized controlled trials involving 1,562 men found that men who received pygeum extract were more than twice as likely to report benefits for healthy bladder function and urinary flow as men who received placebo.* Additionally, this same meta analysis found that side effects associated with pygeum extract were mild and similar to placebo.	Pygeum Bark Extract

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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

11/8/05

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Michael P. Devereux

Mike Devereux
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	While the leaves and stem of the stinging nettle plant (<i>Urtica dioica</i>) have a long history of traditional use for joint and respiratory health, recent research has focused on the health supportive benefits of the roots for healthy urinary flow and prostate function.*	Nettle Root Extract

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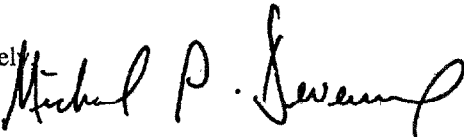
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	Stinging nettle has been shown to support a natural anti-inflammatory response, partially through its inhibition of cyclooxygenase derived reactions.*	Nettle Root Extract

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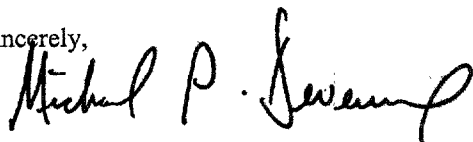
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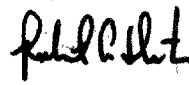
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	A one year, randomized, double blind, placebo controlled study of stinging nettle root extract found that its use was associated with a 30% benefit in urinary and prostate health.*	Nettle Root Extract

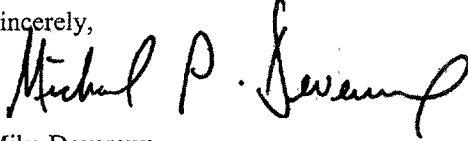
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	In a clinical trial of 134 men taking a blend of stinging nettle and pygeum for 28 days researchers found that this combination provided significant support for healthy urination.*	Nettle Root Extract, Pygeum Bark Extract

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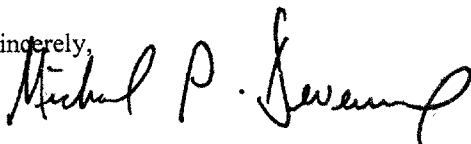
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	Analysis of the naturally occurring compounds in pumpkin have found that it contains high levels of phytosterols, (including beta-sitosterol) as well as linoleic acid, selenium and other beneficial nutrients for bladder and prostate health.*	Pumpkin Seed Oil

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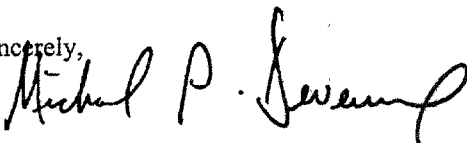
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	Pumpkin's mechanism of action is not completely understood. One theory is that delta-7 sterols in the fatty oils block dihydrotestosterone from androgen receptors, decreasing the exposure of prostate cells to hormonal stimulation.*	Pumpkin Seed Oil

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Title: Senior Vice President of Scientific Affairs

Date: _____

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,

Mike Devereux
Chief Financial Officer



ENZYMATIC THERAPY INCORPORATED

What **Better** feels like.™

November 9, 2005

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	Research has found that pumpkin mildly inhibits 5 alpha reductase (an enzyme which converts testosterone to dihydrotestosterone) <i>in vivo</i> , and supports the body's natural anti-inflammatory response.*	Pumpkin Seed Oil

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

11/9/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,

Mike Devereux
Chief Financial Officer

INTEGRATIVE THERAPEUTICS INC.™

NF Formulas • PhytoPharmica
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 • F: 503.582.0467

ENZYMATIC THERAPY®

&
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 • F: 888.570.6460 (Enzymatic)

P: 920.469.9099 • F: 920.469.4418 (Phyto)



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	In an open clinical trial pumpkin intake was associated with healthy levels of dihydrotestosterone in prostate tissue.*	Pumpkin Seed Oil

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

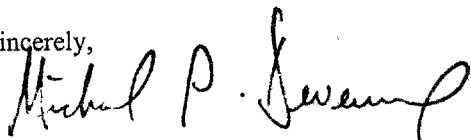
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	In scientific studies pumpkin seed oil was found to support healthy bladder pressure and function.*	Pumpkin Seed Oil

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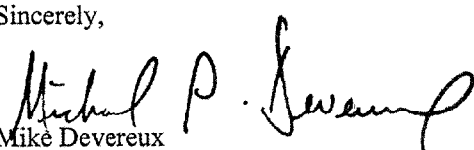
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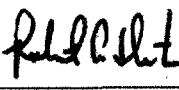
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Better Bladder™* for Men	Each of the herbs in Better Bladder for Men has a long history of traditional use, backed by modern scientific studies showing benefits and safety.*	Nettle Root Extract, Pumpkin Seed Oil, Pygeum Bark Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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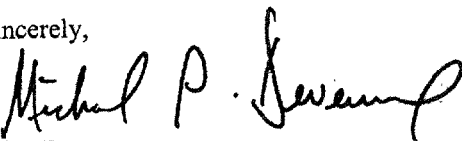
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